

Novocell, Inc.

The logo for Novocell, Inc. features the company name in a white serif font. A light blue swoosh underline begins under the 'N', curves under the 'Novocell' portion, and then extends upwards and to the right, ending under the 'Inc.' portion.

CIRM

Intellectual Property Policy

Stem Cell Company Perspective

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- True biotech opportunity
- 'High risk, high reward driven by innovative technologies to discover novel products and services based on these technologies'
- Potential to produce true disease modifying treatment and cures for many diseases including diabetes
- New era of medicine....
- 2000: 'Cell Century'
- Last frontier?

Why California?

- Hub of Biotechnology Innovation—Stem Cell Talent, Resources, ‘Can-Do Mentality’
- San Diego consortium for regenerative medicine (UCSD, Salk, Scripps and Burnham)
- “Congregation” of Experienced Venture Capitalists
- Prop71/CIRM

- Financial uncertainty
 - Many VC's on the sidelines
- I.P. minefield
- Cell therapy and the FDA
- Timelines for cell products
 - First-in-class uncertainties
- Political/ethical “tensions”

Value of Research Grants to Companies

- Decrease investor risks
 - Many technologies have been monumental disappointments: anti-sense, cancer vaccines, gene therapies, “genomics”...
 - Many technologies have taken time to mature, e.g. monoclonal antibody therapies
- Non-dilutive
- Decrease timelines to clinic
- Allow greater innovation
- Provide peer-review evaluation

- JDRF
 - Steering Committee (2+2)
 - Progress reports (technical + financial) - 6 monthly
 - up to 5 years after finish of grant
 - Reasonable efforts to publish or disseminate results
 - IP owned by Novocell
 - RON to JDRF if Novocell wants to abandon
 - Report third party agreements for up to 10 years

- JDRF
 - Repayment of 3X total funding
 - Based on Product sales “in whole or in part from results of the Research Program”
 - Payment rate of 1% of net sales by Novocell
 - OR 5% of third party payments
 - No repayment if commercialization does not occur
 - Assignment or subcontracting requires prior written consent
 - Except merger or consolidation

Potential IP and Revenue Sharing Models (1)

- JDRF model acceptable
 - Company knows what they are signing up for
 - Not based on IP but product sales or licensing activity
- Royalty model
 - May work if limited to new IP
 - Need for funding of multiple activities (clinical trials, scale up, manufacturing etc)
 - Very complex field probably requiring multiple licenses
 - Anti-stacking provisions
 - unattractive to future partners

Potential IP and Revenue Sharing Models (2)

- Loan
 - Interest bearing but forgivable if no product within X years
 - Messy accounting wise
- Convertible Debt
 - Conversion at option of company
- Exclusive Marketing
 - For a period of time new products offered in CA only
 - stimulates State economy
 - Partners won't like it

Can CIRM Make Uniform Policy for Commercial Entities?

- Difficult
 - Companies at various stages of development
 - Virtual
 - Private, angel investors
 - Private, VC investors
 - Public
 - Different businesses
 - Therapeutics
 - Reagents
 - Diagnostics

Collaborative Consortia

- Needs to be driven by commercial considerations
 - Only work together when all entities have something to gain
 - Corporate culture important
- Companies need to be able to maintain control of confidential information and IP
- Should not be requirement of CIRM
- Could be driven by specific grants
 - more likely to be company/academic collaboration

- How will CIRM protect confidential information divulged in grant applications?
 - NIH model probably won't work
 - Great detail required
 - mostly hypothesis driven
- Prop 71 - Priority for “ stem cell researchunlikely to receive federal funding”
 - Focus on hESC research
 - How will that be administered?
 - How will CIRM handle already existing IP?